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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,343	10/15/2001	Margaret K. Hostetter	110.00280103	4625

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[REDACTED] EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/15/2003

*J*

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/978,343

Applicant(s)

HOSTETTER ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply:

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 18 June 2003.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 28-47 and 49-66 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 36,37,52-54 and 63 is/are allowed.

6) Claim(s) 28-35, 38-47,49-51, 55-62, 64-66 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_

## **DETAILED ACTION**

The amendment filed 6/18/03 has been entered.

### ***Response to Arguments***

The rejection of claims 32, 29, 33, 37 and 42 under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims.

The rejection of claims 44-46 under 35 USC 112, first paragraph, is withdrawn in view of the amendment to the claims, though other claims remain rejected.

The rejection of claims 36 and 37 under 35 USC 102(b) is withdrawn in view of the amendment to claim 36, though other claims remain rejected.

The rejection of claim 48 is moot in view of its cancellation.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

Claims 40-44 remain and amended claim 45 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous Office action (paper mailed 3/21/03) on page 3-4.

Applicants argue that the specification conveys Applicants were in possession of the claimed invention. The argument has been fully considered, but is not persuasive. The claimed invention includes an antibody that binds a polypeptide which is structurally similar to but not identical to SEQ ID NO:2, and has the functional property of blocking *C. albicans* adhesion to epithelial and/or endothelial cells. One cannot readily envision the amino acid sequence of the polypeptide described in the claim if that polypeptide does not have the sequence of SEQ ID NO:2. One cannot make an antibody to a polypeptide one does not have or for which one does not have the sequence.

***Claim Rejections - 35 USC § 102***

Claims 28, 29, 32, 33, 40-42 and 45 remain and claims 30, 31, 34, 35, 38, 39, 43, 44, 46, 47, 49-51, 55-62, 64-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Meinke et al. (Ped. Res., 35(4/2):187A, #1106, April 1994) for the reasons set forth in the previous Office action (mailed 3/21/03, pages 4-5) and for the following reasons addressing the amendment to the claims and rejection of dependent claims.

Claim 38 now is drawn to an antibody to a peptide having (meaning “comprising”) an amino acid sequence of SEQ ID NO:4, 5, 6, 7 or 8. The antibody of claim 38 reads on an antibody that binds the full length SEQ ID NO:2 of which the sequences listed in claim 38 are fragments. Claims reciting *C. albicans* developmental stages (46 and 61-66) and blockage of binding by at least 30% or 50% (30, 31, 35, 39, 43, 44, 47, 50, 51 and 55-57) are also anticipated in light of the evidence as discussed below that OKM1 antibody almost completely inhibited binding of mIAL cells to *C. albicans* hyphae (Forsyth et al., Infect. Immunity. Feb 2002). Therefore, it reasonably appears that OKM1 would inherently have possessed the ability to block binding of at least *C. albicans* hyphae to at least epithelial cells and block *C. albicans* adhesion by at least 50%. Further, if the antigen that OKM1 binds is presented both on hyphae and mature *C. albicans*, it is more likely than not that other developmental stages (blastopores and germ tubes) also present the OKM1 antigen such that it would be bound by the antibody.

Applicants argue that Meinke et al. does not anticipate the instant claims because the reference does not teach or suggest that the antibodies “block *Candida albicans* adhesion to epithelial and/or endothelial cells.” The argument has been fully considered, but is not persuasive. While the reference does not disclose that monoclonal antibody OKM1 inhibited binding of *C. albicans* to endothelial or epithelial cells, the skilled artisan would reasonably have expected that it does. The reasons for this are as follows: 1) mAb OKM1 binds to a lectin site of CD11b located COOH-terminal to the I-domain binding site for iC3b (col. 2, end of second paragraph; Vetvicka et al., J. Clin. Invest. 1996. 98:50-61) and yeast express iC3b; 2) OKM1 almost completely inhibited binding of mouse lymphocytes (mIAL) and CD11b-expressing 3T3-19 fibroblasts to *C. albicans* hyphae (p. 520, beginning of second full paragraph, and p. 522; Forsyth et al., Infect. Immunity. Feb 2002. 70(2):517-527); and, 3) *C. albicans* expresses αιnt1

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and binds iC3b synthesized by epithelial cells (beginning of col. 2, p. 243; Hostetter, M. Trends In Microbiology. June 1996. 4(6): 242-6). Therefore, it reasonably appears that publicly available antibody OKM1 disclosed by Meinke et al. anticipates the claims, absent evidence to the contrary.

Applicants argue that Meinke et al. does not teach an antibody that binds SEQ ID NO:3 (claims 32-34). As disclosed by Forsyth et al., *ibid.*, p. 525 middle of col. 2, OKM1 binds a lectin site. This site was mapped to an area C-terminal to the I-domain apparently near the divalent cation-binding region (*e.g.*, p. 1244, col. 1, second full paragraph; Thronton et al. J. Immunol. Feb. 1996. 156: 1235-1246). Since SEQ ID NO:3 comprises the I-domain as well as the first cation-binding site (SEQ ID NO:4), it reasonably appears that SEQ ID NO:3 comprises the lectin site and, therefore, the epitope bound by OKM1. For these reasons, Meinke et al. is an anticipatory reference absent evidence to the contrary. Note parenthetically that claim 32 does not require blocking of *C. albicans* adhesion to cells.

### ***Conclusion***

Claims 36, 37, 52-54 and 63 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. Please advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

September 15, 2003